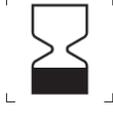
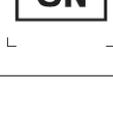


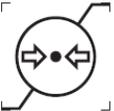
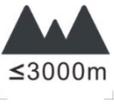
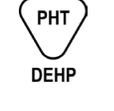
Regulations and standards referenced in the following table are listed at the end of this document.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD(S) and REFERENCE NUMBER
	Prescription only device or product	Indicates a device is for prescription use only. Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	21 CFR 801.15(c)(1)(i)F 21 CFR 801.109
	Medical Device	Indicates the item is a medical device <i>Note: Use specific to European CE-Marked devices</i>	ISO 15223-1:2021 Reference no. 5.7.7 EU MDR 2017/745
	In Vitro Diagnostic Device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device. <i>Note: Use specific to European CE-Marked devices</i>	ISO 15223-1:2021 Reference no. 5.5.1 EU IVDR 2017/746
	CE mark European Conformity	Indicates that a device is in conformity with the applicable requirements set out in European Regulations. CE mark may be accompanied by numerical code designating the Notified Body under which the device is certified. <i>Note: Use specific to European CE-Marked devices</i>	EU MDR 2017/745 EU IVDR 2017/746 EU MDD 93/42/EEC Regulation (EC) 765/2008, Annex II
	Authorized Representative in the European Community/ European Union	Indicates authorized representative in the European Community / European Union <i>Note: Use specific to European CE-Marked devices</i>	ISO 15223-1: 2021 Reference no. 5.1.2
	Importer	Indicates the entity importing the medical device into the market <i>Note: Use specific to European CE-Marked devices</i>	ISO 15223-1:2021 Reference no.5.1.8 ISO 7000-3725
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1: 2021 Reference no. 5.1.1 ISO 7000-3082

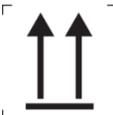
SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD(S) and REFERENCE NUMBER
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1:2021 Reference no. 5.1.3 ISO 7000-2497
	Country of Manufacture	To identify the country of manufacture of products. In the application of this symbol, the "CC" shall be replaced by either the two-letter country code or the three-letter country code defined in ISO 3166-1. Name of manufacturer and date of manufacture may be added adjacent to this symbol. The use of this symbol with a date of manufacture precludes the use of symbol 5.1.3 (Date of Manufacture).	ISO 15223-1:2021 Reference no.5.1.11 ISO 7000-6049
	Use-by date Expiration date	Indicates the date after which the medical device is not to be used	ISO 15223-1:2021 Reference no. 5.1.4 ISO 7000-2607
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO15223-1:2021 Reference no. 5.7.10
	Batch Code Lot Number	Indicates manufacturer's batch code. (lot number, lot code or batch number)	ISO 15223-1:2021 Reference no. 5.1.5 ISO 7000-2492
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1:2021 Reference no. 5.1.6 ISO 7000-2493
	Quantity Package quantity	To indicate the number of pieces in the package	N/A
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1: 2021 Reference no. 5.1.7 ISO 7000-2498

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD(S) and REFERENCE NUMBER
  	<p>Do not re-use</p> <p>Single Use</p> <p>Use Only Once</p> <p>Single Use</p>	Indicates a medical device that is intended for one single use only	<p>ISO 15223-1:2021 Reference no. 5.4.2</p> <p>ISO 7000- 1051</p>
	Single patient multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient	<p>ISO15223- 1:2021 Reference no. 5.4.12</p> <p>ISO 7000-3706</p>
	<p>Consult (electronic) instructions for use</p> <p>Consult operator's manual</p>	Indicates the need for the user to consult the instructions for use	<p>ISO 15223-1:2021 Reference no. 5.4.3</p> <p>IEC 60601-1, Table D.1, Symbol 11</p> <p>ISO 7000-1641</p>
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	<p>ISO 15223-1: 2021 Reference no. 5.4.4</p> <p>ISO 7000-0434A</p>
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	<p>ISO 15223-1:2021 Reference no. 5.2.3</p> <p>ISO 7000-2501</p>
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	<p>ISO 15223-1:2021 Reference no. 5.2.4</p> <p>ISO 7000-2502</p>
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized	<p>ISO 15223-1:2021 Reference no. 5.2.6</p> <p>ISO 7000- 2608</p>
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process	<p>ISO 15223-1: 2021 Reference no. 5.2.7</p> <p>ISO 7000-2609</p>

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD(S) and REFERENCE NUMBER
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device which should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1: 2021 Reference no. 5.2.8 ISO 7000-2606
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223- 1:2021 Reference no. 5.2.11 ISO 7000-3707
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 15223-1: 2021 Reference no. 5.3.1 ISO 7000-0621
	Keep away from heat Keep away from sunlight	Indicates a medical device that needs protection from light sources	ISO 15223-1: 2021 Reference no. 5.3.2 ISO 7000-0624
	Keep dry Keep away from rain	Indicates a medical device that needs protection from moisture	ISO 15223-1: 2021 Reference no. 5.3.4 ISO 7000-0626
	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed	ISO 15223-1: 2021 Reference no. 5.3.5 ISO 7000-0534
	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed	ISO 15223-1: 2021 Reference no. 5.3.6 ISO 7000-0533
	Temperature limits	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1: 2021 Reference no. 5.3.7 ISO 7000-0632

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD(S) and REFERENCE NUMBER
	Humidity limitation	Indicates the range of humidity t which the medical device can be safely exposed	ISO 15223-1: 2021 Reference no. 5.3.8 ISO 7000-2620
	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.	ISO 15223- 1:2021 Reference no. 5.3.9 ISO 7000-2621
	Maximum altitude	To indicate that the appliance is intended to be usable up to the maximum altitude indicated. The letter symbols "3000" may be replaced by those for a different numerical value (in meters) in agreement with actual applications.	ISO 7000-6343
	Contains or presence of natural rubber latex	Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device	ISO 15223-1: 2021 Reference no. 5.4.5 ISO 7000-2725
	Does NOT contain natural rubber latex	Indicates the LACK OF presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device	ISO 15223-1: 2021 Reference no. 5.4.5 ISO 7000-2725 Negation symbol per ISO 80416-3:2002+A1:2011
	Contains or presence of the phthalate: bis (2-ethylhexyl) phthalate (DEHP)	Indicates the presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP) as a material of construction within the medical device	BS EN 15986:2011 Reference no. A.2
	Does NOT contain the phthalate DEHP	Indicates the LACK OF presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP) as a material of construction within the medical device	BS EN 15986:2011 Reference no. A.2 Negation symbol per ISO 80416-3:2002+A1:2011

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD(S) and REFERENCE NUMBER
	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine-disrupting properties	ISO 15223- 1:2021 Reference no. 5.4.10 ISO 7000-3723
	Contains biological material of animal origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin	ISO 15223- 1:2021 Reference no. 5.4.8 ISO 7000-3699
	Magnetic Resonance (MR) safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.	ASTM F2503 Reference no. ASTM F2503; Table 2; 7.4.6.1; Fig. 6, 7
	Magnetic Resonance (MR) conditional	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.	ASTM F2503 Reference no. Tabel 2; 7.4.6.1; Fig 6,7
	Magnetic Resonance (MR) unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment	ASTM F2503 Reference no. Table 2, Symbol 7.3.3; 7.4.9.1; Fig. 9
	Class II equipment	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140	IEC 60417, Reference no. Table D.1, Symbol 9 IEC 60417- 5172
	Type B applied part	To identify a type B applied part	IEC 60601-1, Reference no. Table D.1, Symbol 19 IEC 60417-5480
	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1	IEC 60601-1, Reference no. Table D.2, Symbol 20 (ICE 60417-5333)

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD(S) and REFERENCE NUMBER
	Rechargeable battery	To identify equipment which shall only be used with rechargeable (secondary) cells or batteries, or to identify rechargeable cells or batteries. When shown on a battery holder, the symbol also indicates the positioning of the cells.	ISO 7000-5639
	Battery check	To identify a control to check the condition of a primary or secondary battery or to identify the battery condition indicator.	ISO 7000-5546
	SAFETY SIGN Follow instructions for use Refer to instruction manual/ booklet	SAFETY SIGN: Follow instructions for use Indicates that a specific and unacceptable risk can be avoided by reading (and understanding) the instructions for use. <i>Note: This safety sign contains a specific safety color that shall conform with ISO 3864-1 and ISO 3864-4.</i>	ISO 7010-M002 IEC 60601-1:2005 § 7.2.3; Table D.2, Symbol 10
	WEEE; waste electrical and electronic equipment	To indicate that separate collection for waste electric and electronic equipment (WEEE) is required.	Directive 2012/19/EC ISO 7000-6414
	This way up	To indicate correct upright position of the transport package.	ISO 7000-0623
	Open here	To identify the location where the package can be opened and to indicate the method of opening it.	ISO 7000-3079
	General symbol for recover/recyclable	To indicate that the marked item or its material is part of a recovery or recycling process	IEC-TR-60878 Reference no. ISO 7000-1135

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD(S) and REFERENCE NUMBER
	Authorized Representative in Switzerland	Indicates the authorized representative in Switzerland	ISO 20417 Reference no. 6.1.2 d)
	Authorized Representative in the United Kingdom	Indicates the authorized representative in United Kingdom	ISO 20417 Reference no. 6.1.2 d)
	UK CA mark	Signifies Great Britain technical conformity.	Medicines and Medical Devices Act 2021, Part 4, Chapter 1, Section 16 (1) (f)

1. PURPOSE

2. SCOPE

This scope

3. PROCESS INTERACTIONS

- C-SOP-20000, Document Name
- G-WI-20001, Document Name

4. ASSOCIATED DOCUMENTS

- C-FRM-20001, Document Name
- J-TMP-20001, Document Name

5. REFERENCE DOCUMENTS

- List any applicable standards
- List any applicable standards

6. RESPONSIBILITIES

Quality

Is responsible for

Engineering

Is responsible for

7. ACRONYMS AND DEFINITIONS

DCR	Document Change Request
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Regulations and Standards Referenced:

- ISO 7000, Graphical symbols for use on equipment - Database
- IEC 60417, Graphical symbols for use on equipment – Database
- ISO 15223-1:2021, Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.
- ISO 20417:2021, Medical devices — Information to be supplied by the manufacturer
- IEC 80416-3:2002+A1:2011, Basic principles for graphical symbols for use on equipment – Part 3: Guidelines for application of graphical symbols + Amendment 1
- BS EN ISO 15986:2011, BSI Standards Publication, Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates.
- ASTM F2503-20, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
- EU MDR 2017/745, REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- EU IVDR 2017/746, REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- WEEE Directive 2012/19/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)
- EU MDD 93/42/EEC, COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- Regulation (EC) 765/2008, REGULATION (EC) No 765/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
- Title 21 CFR, Code of Federal Regulations (CFR)